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मानक

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“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

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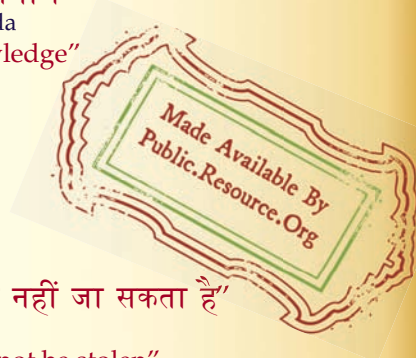
IS 8755 (1977): Method for Testing for Biological Compatibility of Metals for Surgical Implants [MHD 2: Orthopaedic Instruments, Implants and Accessories]



“ज्ञान से एक नये भारत का निर्माण”

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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard

METHOD FOR TESTING BIOLOGICAL COMPATIBILITY OF METALS FOR SURGICAL IMPLANTS

(Reaffirmed 1992)

1. Scope — Prescribes procedure for testing biological compatibility of metals used for surgical implants.

2. Test Hosts

2.1 Rats, rabbits and dogs are to be used for muscle implantation in accordance with the schedule shown in 3.5.

2.2 Rabbits and dogs shall be used for bone implantation in accordance with the schedule shown in 3.6.

3. Test Specimens

3.1 Machining, finishing, and surface preparation of test coupons shall be accomplished in accordance with 3.5. The coupons shall be prepared as they would be for use as implants in human subjects. Each coupon shall be of high internal quality and shall be checked in accordance with IS : 5347-1969 'General requirements for metal surgical implants'.

3.2 Coupons for Insertion in Muscles

3.2.1 For rats, use 1.6 mm diameter and 6.3 mm long cylindrical coupons.

3.2.2 For rabbits, use 3.2 mm diameter and 12 mm long cylindrical coupons.

3.2.3 For dogs, use 9.5 mm diameter and 25 mm long cylindrical coupons.

3.3 Coupons for Insertion in Bones

3.3.1 For rabbits, use 1.6 mm diameter and 12 mm long cylindrical coupons.

3.3.2 For dogs, use 3.2 mm diameter and 12 mm long cylindrical coupons.

3.4 Prepare a set of control coupons from any of the alloys conforming to IS : 5347-1969.

3.5 For muscle implantation there shall be a sufficient number of animals so that at the stage of retrieval, number of animals designated in 5.2.1 are available:

Animal	Minimum Number of Animals	Number of Specimens in Each Animal
Rat	20	One control coupon plus one test coupon on each side of spine (maximum of six per animal)
Rabbit*	12	One control coupon plus two test coupons on each side of spine (maximum of six per animal)
Dog*	3	Two control coupons plus four test coupons on each side of spine (maximum of twelve per animal)

3.6 For bone implantation there shall be a sufficient number of animals so that at the stage of retrieval, number of animals designated in 5.2.2 are available for sacrifice:

Animal	Minimum Number of Animals	Number of Specimens in Each Animal
Rabbit†	6	One control coupon plus two test coupons in each femur (maximum of six per animal)
Dog†	3	Two control coupons plus four test coupons in each femur (maximum of twelve per animal)

*One control for every two test coupons in rabbits and dogs.

†One control for every two test coupons.

Adopted 9 November 1977

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Price Rs. 6.00 Gr 2

4. Conditioning

4.1 After final preparation by the manufacturer, handle the coupons with great care so that the coupons do not get damaged or scratched in any way, prior to insertion in an animal. This especially applies to damage from contact with metal instruments.

4.2 Prior to sterilization, carefully degrease the coupons and then wash them in strong detergent; thoroughly rinse in distilled water; and dry in a series of alcohol and other solutions. Sterilize the coupons in a manner that will not adversely affect the corrosion resistance of the alloy and then place them in a sterile nonabrasive package identified with the series number of the implant material and with the individual number of the coupon. Sterilization may be done in dry heat or by ethylene dioxide exposure methods.

5. Procedure

5.1 *Implantation*

5.1.1 Place coupons in the back muscles of adult rats, rabbits, and dogs in such a manner so that they are directly in contact with muscle tissue. Under sterile conditions, make a bed in the muscle by using a hemostat to separate the muscle fibres and then insert the implant using plastic tipped forceps to avoid damage to the implant. Having inserted one control and one experimental coupon on each side of each rat, close the wound. Follow an analogous muscle implantation procedure for rabbits and dogs, allowing for larger numbers of experimental coupons to be inserted and multiple insertions through a single incision as permitted by the size of the animal. No rabbit shall receive more than six implanted coupons, and no dog shall receive more than twelve.

5.1.2 Expose the lateral cortex of each rabbit femur and drill three holes through the lateral cortex only on each side. For dogs, the holes shall be 3.2 mm in diameter. Six holes in each femur may be made. Insert one of the coupons by finger pressure into each one of these holes. Then close the wound. At least one control coupon for every two experimental coupons in rabbits and dogs shall be available.

5.2 *Retrieval*

5.2.1 For surgical retrieval of specimens implanted in muscles, incise the skin at the back using surgeon's scissors, and remove each coupon with its surrounding muscle, to the extent of at least 9.5 mm, if possible, using a sharp scalpel or preferably a platinum-iridium knife blade or suitable glass knife.

5.2.1.1 Sacrifice the animals at the following intervals after insertion: four rats at 2, 4, 8, 12 and 26 weeks; two rabbits at 2, 4, 8, 12, 52 and 104 weeks. Retrieve specimens from dogs at 26, 52 and 104 weeks, the total number of test coupons for each time interval to be not less than eight, and to be derived from at least two dogs. One control coupon shall be available for each rat coupon, one control coupon for every two rabbit coupons, and one control coupon for every two coupons in dogs. Specimens may be retrieved by surgical removal without sacrifice of the dogs.

5.2.2 At sacrifice, remove the femora; clean, and take tissue specimens analogous to these described for muscle. Sacrifice the animals at the following intervals: 2, 4, 8, 12, 52 and 104 weeks for rabbits, and 26, 52 and 104 weeks for dogs. The number of specimens for each time interval will be three for rabbits and eight for dogs.

5.2.3 Part of the samples from dogs or rabbits may be excised for spectrographic or electron probe analysis. Fix them in 10 percent formalin or other fixative, following which remove the coupon and submit the tissue specimen to elective special studies.

5.3 *Inspection*

5.3.1 Inspect implants and surrounding tissue for evidence of corrosion directly (after removal) by the naked eye, hand lens, and microscope with at least 20× magnification.

5.3.2 For histological study, prepare and stain at least two sections of the tissue surrounding each coupon. Measure the thickness of the scar and ascertain the presence or absence of neoplastic change.

5.3.3 If any animal in any group does not survive the schedule time interval, or if infection or fracture vitiates the histological specimens of any animal, replace that animal by an alternate so that the number of retrieved specimens will be at least that represented in 3.3.

6. Interpretation of Results

6.1 Note any evidence of discoloration, tarnish, or corrosion on any of the metal coupons after removal. Note any loss of metal to the tissues as judged by unmistakable brown or black discoloration of the tissue enveloping the coupon compared to the control specimen even in the absence for the test metal will be defined as an equal or lesser effect on surrounding tissue or metal corrosion than shown by the control metal.

6.2 For the histological studies, adequate tolerance is defined as an equal or lesser degree of cellular reaction or thickness of scar or both, and the absence of neoplastic change in the accumulated inter-comparisons between controls and experimental coupons from all the experimental intervals. In an exceptional situation, when a total of fewer than six experimental coupons from all the coupons of a given material have produced an increased cellular reaction or thickness of scar in the tissue surrounding them, repetition of these items of the test with double the numbers of animals involved may be allowed to be substituted for the exceptional histological specimens. If the repeated items in the test then demonstrate tolerance as defined, the completed test will then be concluded with the judgement that the material tested is as well tolerated as the control material.

7. Report

7.1 The report shall include the observations of each control and test coupon as well as the observation of the surrounding tissue to which the coupons were implanted.

7.2 The report shall include the observations of each histological examination.

7.3 A comparison between the control coupons and the test specimens together with a statement declaring the acceptability of the test material or the inferiority to the control material shall also be reported.

EXPLANATORY NOTE

This standard provides method for testing the biological compatibility of metals so that new alloys may be approved for use in surgical implants designed for orthopaedic treatment or designed to be used in contact with body fluids. Currently accepted materials were standardized on the basis of acceptable experience of orthopaedic surgeons. The method prescribed for assaying new materials is based on a comparison with current standards.